UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOPURE CORPORATION SECURITIES LITIGATION	)	**Master Docket No. 1:03-CV-12628 (NG)**
	)	**Assigned to Judge Nancy Gertner**

DEFENDANTS' MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION TO AMEND
THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

BIOPURE CORPORATION, THOMAS A. MOORE, HOWARD P. RICHMAN, RONALD RICHARDS CARL W. RAUSCH, CHARLES A. SANDERS and J. RICHARD CROUT

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Preliminary Statement[1]

The Plaintiffs' last minute motion for leave to amend (filed seven days prior to the originally scheduled hearing on the motion to dismiss) is predicated on an attempt to copy allegations made by the Securities and Exchange Commission ("SEC") in a separate proceeding. Such allegations copied from another pleading *cannot* be accepted by the Court as a matter of law for the purposes of determining the sufficiency of the proposed amended complaint. Furthermore, even with the copied allegations, the proposed complaint fails to state a claim, is futile, and should not be allowed.[2]

Rule 11, the hearsay rule and the limits of judicial notice have all guided courts in rejecting the same tactic employed by the Plaintiffs here. A party cannot portray as *allegation of fact* what is merely an *allegation from another pleading*. The proposed amended complaint, like the pending complaint, is pled on "information and belief." Accordingly, Plaintiffs must state both the *source* of information and the *reason* for the beliefs under the Private Securities Litigation Reform Act ("PSLRA"). With the exception of quotes attributed to SEC filings, the Plaintiffs' prolix (near 100 pages) complaint fails to identify both the "source" -- *which* allegations are derived from the SEC (and thus superfluous) -- as well as the reasons for the

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[1] This Memorandum of Law in Opposition to Plaintiffs' Motion to Amend the Complaint (the "Motion") is respectfully submitted by Defendants Biopure Corporation ("Biopure" or the "Company"), Thomas A. Moore, Howard P. Richman, Carl W. Rauch, Charles A. Sanders and J. Richard Crout (collectively, the "Defendants" or Messrs. Moore, Richman, Rausch, Sanders and Crout as the "Individual Defendants")

[2] As many of the theories and allegations in the proposed amended complaint also appear in the pending complaint subject to the Defendants' pending motion to dismiss, for the sake brevity, Defendants will not repeat the fulsome analysis of their motion to dismiss, but rather, incorporate it by reference here.

belief, *i.e*. an independent corroborating investigation sufficient under Rule 11. As pled, none of the Plaintiffs' unattributed allegations can be accepted as true under the PSLRA, because none identifies whether it is based on some potentially sufficient source, as opposed to mere allegations in another proceeding that cannot be considered as a matter of law.

Even if, *arguendo*, the proposed complaint pled any basis for the information and belief allegations asserted (and it does not), the proposed complaint also fails -- despite full notice through previous briefing on Defendants' Motion to Dismiss -- to rehabilitate the pending complaint's deficient allegations of *scienter*. Plaintiffs' sole new *scienter* allegation asserts (based on information and belief without attribution) that a Biopure employee (not a Defendant) made a statement to a single investor concerning certain FDA correspondence. The allegation is not about any Defendant and does not include any basis by which the statement could be attributed to any Defendant. The proposed complaint also continues to contain virtually no allegations whatsoever about defendants Sanders, Richards, Crout and Rausch -- impermissibly attempting to plead *scienter* simply by virtue of their corporate positions -- and still fails to include allegations of fact deemed necessary by this Court to support any inference of *scienter* based on insider trading with respect to Rausch.

Moreover, nothing in the proposed amended complaint changes the fact that there was no duty to disclose the FDA's clinical hold on a single proposed study to test Biopure's product, in-hospital, on patients who suffered traumatic injury. The proposed complaint makes basically the same allegations concerning the back and forth communications between the Company and the Food and Drug Administration ("FDA") regarding that single proposed study. There is no legal duty to disclose such back and forth in the clinical trial development process. Indeed, some Courts have stated that such disclosure could be irresponsible.

The Plaintiffs also raise a new theory in the proposed complaint, quibbling that the Company should have disclosed that a letter it received from the FDA on July 30, 2003 concerning the BLA (the "BLA Letter") was a "complete response letter" ("CRL"). The theory is remarkable in that FDA itself did not label its own letter a CRL,[3] and FDA itself has instructed that "*[i]ssuance of complete response letters . . . [carry] no implication as to the ultimate approvability of the application.*" In any event, the Plaintiffs' new theory is predicated on an assumption that Biopure had a duty to speculate about what the FDA might have meant by its BLA Letter concerning future events, and then make public disclosure about it. There is no such duty.

In all other respects, the proposed complaint replicates the pending complaint's allegations and is subject to dismissal for the same reasons as stated in the Defendants' Memorandum of Law in Support of their Motion to Dismiss and Reply (*i.e.* failure to satisfy rule 9(b) and failure to surmount the PSLRA's safe harbor for forward looking statements). Those arguments are incorporated here by reference.

[3] A copy of the letter is attached to the proposed second amended complaint as Exhibit B. It never once says it is a "Complete Response Letter."

ARGUMENT

I. THE PLAINTIFFS' ATTEMPT TO ADOPT THE SEC'S ALLEGATIONS REQUIRES DISMISSAL AS A MATTER OF LAW -- THE PROPOSED AMENDED COMPLAINT IS FUTILE

In considering whether leave to amend may be granted under Rule 15, courts are cautioned to consider, *inter alia*, whether "the proposed pleading is futile in that it *adds nothing of substance to the original allegations* . . . ." *Lewis v. Knutson*, 699 F.2d 230, 239 (5th Cir. 1983) (emphasis added) (affirming denial of leave to amend derivative complaint). "Liberal amendment is the norm, but that liberality does not extend to the superfluous." *Sprague v. United Air Lines, Inc.*, No. Civ. A.97-12102 2000 WL 621112 (D. Mass. May 3, 2000)[4]. The Plaintiffs' proposed amendment to add superfluous allegations that are not cognizable under Rule 11, the hearsay rule or principles of judicial notice, should be denied.

A. Under Rule 11, The Limits Of Hearsay And Judicial Notice, This Court Cannot Accept The SEC's Allegations On This Motion

The Plaintiffs cannot simply adopt the SEC's allegations as their own, and this Court cannot accept those allegations as true for purposes of a Rule 12(b)(6) motion. Numerous courts have rejected similar attempts to tag along with SEC enforcement actions, on a variety of legal grounds.

Rule 11 imposes a non-delegable duty upon the signing attorney to conduct his own independent analysis of the facts and law which form the basis of a pleading or motion. *See Pavelic & LeFlore v. Marvel Entertainment Group*, 493 U.S. 120, 125-27 (1989) (signing attorney cannot rely on the analysis of a member of his law firm to have ascertained the facts). Unsurprisingly then, courts have outright rejected plaintiffs' attempts to bolster their otherwise

[4] All unreported cases are submitted herewith in the Compendium of Unreported Authorities Cited in Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Amend the Consolidated Amended Class Action Complaint.

deficient civil fraud actions by reference to SEC proceedings. For instance, in *Geinko v. Padda,* No. 00 C 5070 2002 WL 276236 (N.D. Ill. Feb. 27, 2002) the court rejected as insufficient under Rule 11 the plaintiffs' incorporation by reference of allegations in complaints filed by the SEC without delineating who alleged what:

> The pervasive defect in the Amended Complaint…is that it does not make clear what Plaintiffs directly allege as fact, and what Plaintiffs merely are asserting that someone else has alleged. In other words… Plaintiffs' attorneys cannot shirk their Rule 11 obligation to conduct an appropriate investigation into the facts that is reasonable under the circumstances by merely stating that "the SEC alleges" certain additional facts.

Id., at *6 (emphasis added).

Commanding a similar result on different grounds, the court in *Nolte v. Capital One Fin. Corp.*, 390 F.3d 311 (4th Cir. 2004), affirming denial of leave to amend a dismissed securities fraud complaint, rejected the appellant/shareholder's request that the court take judicial notice of facts alleged in an SEC complaint:

> The shareholders have asked the Court to take judicial notice of the [SEC's] complaint and the facts alleged therein. Only indisputable facts are susceptible to judicial notice. Although the filing of an SEC complaint against Willey is indisputable, the facts alleged therein are not. A court cannot take notice of (and so assume the truth of) mere allegations that Capital One or its management made false statements or omissions during the class period.

Id. at 317, n.*.

Likewise, in *Reding v. Goldman Sachs & Co.*, 382 F. Supp. 2d 1112 (E.D. Mo. 2005), the court rejected the plaintiffs' attempt to rely upon SEC allegations through incorporation by reference of the SEC's complaint (as do Plaintiffs here) because hearsay -- *i.e*. the SEC's allegations -- adds nothing to the complaint:

> The plaintiffs have incorporated the SEC Complaint as the "factual basis" for their allegations of fraud, negligent misrepresentation, violation of state securities law, and violation of federal securities law. Essentially, they are asking the Court to accept this document for the "truth of the matters asserted therein" in consideration of the instant motion. *This the Court cannot do.*

Id. at 1115 (emphasis added).

B. The Proposed Amended Complaint (As Well As The Pending Complaint) Cannot Survive A Motion To Dismiss Due To Plaintiffs' Failure To Identify All Facts As The Source Of Information And Belief

The PSLRA *requires* that a complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, *if an allegation regarding the statement . . . is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.*" 15 U.S.C. § 78u-4(b)(1) (emphasis added). This means that "[i]f the plaintiff brings his claims on information and belief, he must 'set forth the source of the information and the reasons for the belief.'" *In re Art Tech. Group, Inc. Sec. Litig.*, 394 F. Supp. 2d 313, 317 (D. Mass. 2005) (citations omitted). Apart from allegations quoting from SEC filings, the proposed amended complaint utterly fails in this regard (as does the pending complaint) and is futile for failure to state a claim.

Preliminarily, the proposed amended complaint is admittedly predicated upon investigation of counsel and information and belief, based on "publicly available information relating to the investigation by the [SEC]" and the complaint filed by the SEC. Prop. Compl., p. 1. That is the complete extent of Plaintiffs' attribution of source information for all allegations in the complaint (excepting quotes from SEC filings and the like) -- patently insufficient under the PSLRA. Indeed, Plaintiffs never even allege *which* allegations are derived from the SEC's complaint, and the Plaintiffs fail to allege a scintilla of basis for allowing this Court, in contradiction with other courts faced with the same problem (*see* above), to accept the allegations as true. Because copying allegations in the SEC complaint does not amount to sufficient allegations as a matter of law, relying on the SEC complaint here cannot save this

amended pleading.

In the First Circuit, the standard for satisfying the PSLRA's requirements concerning information and belief allegations is exacting. For instance, in *Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235, 247 (D. Mass. 2001), this Court dismissed out of hand a complaint that pled far more by way of source material for the plaintiffs' information and belief allegations:

> [T]he plaintiffs advert to an investigation of their counsel that included "(i) an analysis of publicly-available news articles and reports; (ii) review and analysis of public filings including, but not limited, to the corporate defendants' annual and fiscal quarterly reports; (iii) press releases issued by defendants; and (v) other matters of public record." With the possible exception of the CTP's annual and fiscal quarterly reports, *the plaintiffs do not identify with specificity the material reviewed and analyzed by their counsel*. And even as to the annual and quarterly fiscal reports, the plaintiffs fail to state which reports were examined. Furthermore, *as to all the sources of information alleged to have been the subject of inquiry by the plaintiffs' counsel, the plaintiffs fail to set out with particularity what information counsel discovered in their inquiry, where that information was discovered, and how the information led to the belief that the defendants had engaged in fraudulent conduct.*

Id. at 247 (emphasis added). The proposed amended complaint, along with the pending complaint, do not satisfy this standard.

Indeed, this Court has flatly refused to accept statements in hearsay documents as providing a basis for information and belief allegations in securities fraud litigation, as the Plaintiffs attempt here. In *Garvey v. Arkoosh*, 354 F. Supp. 2d 73 (D. Mass. 2005), for instance, this Court, relying on the PSLRA, held that the complaint would be dismissed because the third party quotes from newspaper articles relied upon amounted to hearsay and thus could not, as a matter of law, provide that basis:

> [T]he allegations of a link between that payment and the supposed "secret funneling' of bribes to the stock analysts is based for the most part on *third party quotes extracted from newspaper articles*. The Amended Complaint is bereft of specific statements or acts attributed to the defendants as opposed to generalities and *hearsay-derived speculation*. The pleading deficiencies of the Amended Complaint are by themselves a sufficient ground on which to base a dismissal.

Id. at 82 (emphasis added).

The same reasoning and result applies here. Aside from quotes in the proposed complaint that are directly attributed to SEC filings, press releases and other publicly available documents, the proposed complaint is silent on the bases for its allegations, except to say that they are based on the SEC's complaint. As the SEC's complaint cannot serve as the bases for the proposed complaint here, the Plaintiffs have failed to sufficiently plead either a source for their information or a reason for their belief. "Where, as here, the complaint fails to 'set forth the source of the information and the reasons for the belief,' the complaint must be dismissed." *In re Art Tech. Group, Inc. Sec. Litig.*, 394 F. Supp. 2d at 317.

C. In Addition, The SEC's Allegations Concern Only Two Individual Defendants Here --The Proposed Amended Complaint Fails To Particularize Conduct Attributable To Each Defendant

The PSLRA and Rule 9(b) require Plaintiffs to "distinguish among those they sue and enlighten each defendant as to his or her part in the alleged fraud." *Coates v. Heartland Wireless Communications, Inc.*, 26 F. Supp. 2d 910, 914 (N.D. Tex. 1998); *In re Stratus Computer, Inc. Sec. Litig.*, 1992 WL 73555 *6 (D. Mass. Mar 27, 1992) (dismissing 10b-5 claims on Rule 9(b) grounds: "The factual allegations simply do not make reference to [individual defendants], except to identify their status. There is no allegation as to what information they knew but did not disclose.") As in the pending complaint, the proposed complaint largely attributes statements

and alleged knowledge of their falsity to the "defendants" as a whole -- in violation of the PSLRA and Rule 9(b).[5]

Importantly, even if the SEC's allegations could be accepted as true here -- and they cannot -- those allegations do *not* allege fraud against any individual beyond those named in the SEC's complaint (Moore and Richman). In *In re Spiegel, Inc. Sec. Litig.*, 382 F. Supp. 2d 989 (N.D. Ill. 2004), the plaintiffs relied upon an Independent Examiner's Report that directly concerned the company only, in an attempt to support allegations concerning the individual defendants. The court properly rejected that tactic, holding "that Plaintiffs must specify the particular defendants responsible for each particular act and cannot simply attribute to 'defendants' conduct that clearly could not encompass all Defendants in this case. *To the extent Plaintiffs attribute conduct or knowledge to [the company], moreover, it may not serve as a basis for imputing the same conduct or knowledge to Defendants,* absent some factual support." *Id.* at 1013.

So too here, the SEC's complaint concerning Biopure, Moore and Richman may not be attributed to the other defendants here who are not named in that action -- Sanders, Crout, Rausch and Richards.

II. THE PROPOSED COMPLAINT FAILS TO RAISE A STRONG INFERENCE OF *SCIENTER*

Nothing in the proposed complaint rehabilitates the Plaintiffs' previously deficient allegations of *scienter*.[6] The Plaintiffs' sole new *scienter* allegation concerning an alleged email

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[5] For example, the Plaintiffs allege that "the Individual Defendants and Biopure [*i.e.* all defendants] had actual knowledge of the FDA's safety concerns and the clinical hold on the Trauma Clinical Trials throughout the Class Period and actual knowledge of the Complete Response Letter as of July 30, 2003.'" Prop. Compl. ¶198. Yet Plaintiffs make no allegations concerning *what each* Individual Defendant knew, and *when*, to support any inference that *each* knew something that allegedly was not disclosed.

[6] In paragraphs 108 and 109 of the pending complaint, Plaintiffs alleged that *scienter* may be inferred because the SEC staff initiated an investigation. Plaintiffs now add that the SEC has commenced an enforcement proceeding. For the same reasons that the Plaintiffs' previous allegation was deficient, so too are the allegations concerning an enforcement proceeding (against only two of the Individual

written by Biopure's Director of Corporate Communications (who is neither an officer nor director nor a defendant in this action) can provide no inference of *scienter* for any of the Individual Defendants. Prop. Compl. ¶ 194. In short, an allegation concerning the state of mind of an employee cannot be attributed to the state of mind for the Individual Defendants. The allegation is superfluous.

Otherwise, the proposed complaint, with its new "allegations" copied from the SEC's complaint, fails to sufficiently allege *scienter* for the Company or any of the Individual Defendants. First, with respect to defendants Sanders, Rausch, Crout and Richards, the proposed complaint's adoption of the SEC's allegations is superfluous -- the SEC's complaint is directed *only* at two of the Individual Defendants here, Moore and Richman. Nothing in the Plaintiffs' allegations about what the SEC has alleged can apply to Individual Defendants Sanders, Rausch, Crout and Richards, and the proposed complaint includes nothing independent of these allegations that could provide a strong inference of *scienter*.

With respect to the Company, Moore and Richman, the proposed complaint is also deficient. The gravaman of this action attacks statements concerning future potential indications of Hemopure in a trauma setting along with the future likelihood of approval of the BLA. Critically, the complaint does not include a single allegation of fact to show that either (i) the Company was precluded from developing a trauma indication or (ii) that the BLA would not be approved. Nor does the complaint include a single allegation of fact showing that the Company, Moore or Richman believed otherwise. The Plaintiffs have failed to allege any intent to deceive.

Defendants here) inadequate. The Plaintiffs' other *scienter* allegations (Prop. Compl. ¶¶ 186, 187, 190-93) are the same as in the pending complaint, and fail for the same reasons provided in the Defendants' previous submissions.

A. An Alleged Statement By A Non-Defendant, Non-Management Employee In An Email To An Investor That The July 30 BLA Letter Was Not A Complete Response Letter Provides No Basis For Any Inference Of *Scienter*

The Plaintiffs' sole additional *scienter* allegation asserts that *scienter* may be inferred based on an alleged email, written by Biopure's Director of Corporate Communications, informing an investor that a reference in an SEC filing to the BLA Letter as a CRL was a mistake. Prop. Compl. ¶ 194. The allegation provides no inference of *scienter*. Even if the PSLRA's pleading requirements did not effectively erase the allegation for Rule 12(b)(6) purposes,[7] a statement made by the "Director of Corporate Communications" -- an individual who is *not* alleged to be an officer or director of the Company and is in any event, *not* a defendant, can provide no basis for raising any inference of *scienter with respect to the Defendants* as a matter of law. *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 366 (5th Cir. 2004) (holding that securities laws do not recognize a theory of collective *scienter*: "the required state of mind must actually exist in the individual making (or being a cause of the making of) the misrepresentation, and may not simply be imputed to that individual on general principles of agency"). Indeed, there is no fact pled to show that any Defendant was even aware of the alleged communication by the employee.

Furthermore, on its face, the email is not an allegation of *scienter* at all. Even when assumed to be true at this stage, the allegation shows only that an email was sent explaining that a reference in a filing was a mistake -- it provides no inference of fraudulent intent on anyone's behalf.

B. The Proposed Amended Complaint Fails To Raise Any Inference of *Scienter* As To Sanders, Crout, Rausch and Richards

The proposed complaint is devoid of allegations that could support any inference, let alone a strong inference, of *scienter* on the part of defendants Sanders, Richards, Crout and

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[7] The allegation cannot be considered on this motion because it is made on "information and belief" without any allegation as to the source of the information or basis for the belief. The allegation appears to be copied from the SEC's complaint which is not subject to the PSLRA and which itself includes no factual basis that could satisfy the PSLRA's requirements. On that ground alone, the Plaintiffs' newly alleged basis for inferring *scienter* is a non-starter.

Rausch. As noted, the allegations copied from the SEC's complaint are irrelevant to these defendants, as they are not named in the SEC action. In any event, the proposed complaint is practically devoid of allegations of any nature concerning these defendants, let alone allegations going to their state of mind.

The *entire extent* of the Plaintiffs' allegations directly concerning Sanders, Richards, Rausch and Crout include only the following:

- These defendants held Board or officer positions at Biopure, Prop. Compl. ¶¶ 24, 25, 27, 28;
- These defendants signed certain SEC filings, Prop. Compl. ¶¶ 56, 58, 87, 168, 190;
- The SEC recommended enforcement action against these defendants (though they are *not* named as defendants in the SEC's complaint), Prop. Compl. ¶¶ 169, 189;
- These defendants were allegedly "control persons", Prop. Compl. ¶ 219.

Other than these allegations, the Plaintiffs also allege that Richards "participated" in certain conference calls, though he personally made no allegedly misleading statements during the calls, Prop. Compl. ¶¶ 72, 75, 83, 85, 119, 149 and that Rausch engaged in insider trading.

Holding board positions and signing SEC filings alone is plainly insufficient to allege *scienter*.[8] Similarly, the fact that the SEC recommended enforcement proceedings cannot establish *scienter* (as explained in Defendants' previous submissions). Indeed, to the extent that the SEC's actions could have any bearing on the issue (and they may not) the sole new allegation here concerning the SEC -- that it brought an enforcement action after a two year investigation

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[8] *E.g.*, *Lirette v. Shiva Corp.*, 27 F. Supp. 2d 268, 283 (D. Mass. 1998) (rejecting allegations of *scienter* that "consist[ed] solely of general inferences that defendants, by virtue of their position within the company, 'must have known' about the company's problems when they undertook allegedly fraudulent actions."); *Cheney v. Cyberguard Corp.*, No. 98-6879-CIV-GOLD 2000 WL 1140306, *9 (S.D. Fla. July 31, 2000) ("it is well-established that '[a]llegations that a director or officer signed public disclosures and/or was involved in the company's daily operations, standing alone, will not satisfy the pleading requirements of the PSLRA or Rule 9(b).'").

that *did not* include Sanders, Richards, Rausch or Crout -- would tend to *negate* any inference of *scienter* for these defendants.

With respect to the Plaintiffs' allegations that Defendant Richards "participated" in certain conference calls, though he personally made no allegedly misleading statements during the calls, Prop. Compl. ¶¶ 72, 75, 83, 85, 119, 149, the allegations in no way show that Richards had any knowledge of any FDA communications that allegedly rendered any statements on the calls misleading. *In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 57 (D. Mass. 1998) ("A 10b-5 plaintiff must allege 'details of [defendants'] alleged fraudulent involvement,' including specifics as to what defendants had knowledge of and when. To satisfy this requirement, complaints typically identify internal reports, memoranda, or the like, and allege both the contents of those documents and defendants possession of them at the relevant time.") The allegation is, in effect, no different than an allegation that a defendant merely signed an allegedly false SEC filing without any allegation concerning the defendant's knowledge of falsity, patently insufficient to allege *scienter*.

Finally, the Plaintiffs' allegations concerning Defendant Rausch's insider trading continue to fail to raise any inference of fraudulent intent. Despite the fact that this would be the Plaintiffs' third complaint, they have still failed to adequately plead sufficient facts concerning Defendant Rausch's trading. While the Plaintiffs plead the bare fact that Individual Defendant Rausch sold stock during the Class Period, the Complaint is devoid of any allegations to show that such trading was unusual or suspicious. As Judge Young has held, "[o]ne fact necessary to a showing of unusualness is the amount of trading that the insider conducted before or after the class period." *In re Peritus Software Services, Inc. Sec. Litig.*, 52 F. Supp. 2d 211, 224 (D. Mass. 1999). The proposed complaint is devoid of this critical information and accordingly fails

to allege *scienter* for Rausch. *Lirette*, 27 F. Supp. 2d at 282 (Complaint failed to set forth the amount of trading conducted by member of board before or after the class period and thus allegations about trades did not support the requisite strong inference of *scienter*.). Moreover, Rausch's sales, allegedly totaling 33.7% of his holdings, are not suspicious. *See In re Peritus Software Serv. Inc*, 52 F. Supp. 2d at 228 (sale of up to 38% of holdings are not suspicious). Nor is the timing of the sales suspicious, with the last sale *four* months prior to the December 24, 2003 press release.[9]

Importantly, there are *no* allegations of *any* trading by Messrs. Crout, Moore, Richards, Richman or Sanders -- *five* of the six Individual Defendants. That circumstance alone tends to negate an inference of *scienter*. *See e.g., In re PEC Solutions Sec. Litig.*, No. 03-CV-331 2004 WL 1854202 *15 (E.D. Va. May 25, 2004) (fact that only one of the individual defendants engaged in trading tended to negate *scienter*).

In fact, some on the Company's Board, including Defendant Sanders and non-defendant Koop, *bought stock* during the period (and *after* the stock price allegedly rose due to alleged misrepresentations), a factor which courts have held tends to negate any inference of *scienter*. (*E.g.* C. Everett Koop MD August 6, 2003 and August 11, 2003; Charles Sanders August 7, 2003, attached hereto as Ex. A) *E.g., In re Humphrey Hospitality Trust, Inc. Sec. Litig.*, 219 F. Supp. 2d 675, 686 (D. Md. 2002) ("A defendant's purchase of stock also undermines an inference of *scienter*."); *In re Century Business Services Sec. Litig.*, No. 1:99CV02200 2002 WL

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[9] *In re Focus Enhancements, Inc. Sec. Litig.*, 309 F. Supp. 2d 134 (D. Mass. 2001) ("the timing of the insider trading does not appear very suspicious. The sales did not occur before a big 'event' unknown to the public.") *see also In re Nike, Inc. Sec. Litig.*, 181 F. Supp. 2d 1160, 1169 (D. Or. 2002) (two-month gap between sales and adverse disclosure negates *scienter*); *Nursing Home Pension Fund v. Oracle Corp.*, 242 F. Supp. 2d 671 (N.D. Cal. 2002) (no inference of fraud where sales took place two months before negative disclosures); *In re Party City*, 147 F. Supp. 2d 282, 313 (D.N.J. 2001) ("A broad temporal distance between stock sales and disclosure of bad news defeats any inference of *scienter*").

32254513 *7 (N.D. Ohio Jun 27, 2002) (stock purchases during class period at allegedly inflated prices inconsistent with *scienter*); *In re Sunterra Corp. Sec. Litig.*, 199 F. Supp. 2d 1308, 1329 (M.D. Fla. 2002) (stock purchase during class period undermines *scienter*); *Schuster v. Symmetricon, Inc.*, 2000 WL 33115909, *7 (N.D. Cal. Aug. 1, 2000) (purchase of stock at allegedly inflated prices undermined a finding of *scienter*).

C. The Plaintiffs' Information And Belief Allegations Concerning Biopure, Moore And Richman Fail To Show An Intent To Deceive

With respect to Defendants Biopure, Moore and Richman, the proposed complaint fails to allege sufficiently any intent to deceive that could pass muster under the PSLRA. As explained above, the proposed complaint is made on information and belief, largely derived from the SEC's complaint. Wholly apart from the fact that Plaintiffs' information and belief allegations are, for Rule 12(b)(6) purposes, superfluous to the extent they are derived from the SEC's complaint (*see* Part I, above), mere information and belief allegations are insufficient to raise the requisite strong inference of *scienter* under the PSLRA.[10]

Scienter is an "intent to deceive." Even if the Plaintiffs can be deemed to have alleged a sufficient basis for asserting that defendants Moore and Richman knew about the clinical hold on the proposed trauma study or that they knew that the FDA deemed its July 30, 2003 BLA Letter to be a "complete response letter," the Plaintiffs have pled nothing to give rise to a strong inference that these defendants' statements allegedly omitting such information was made with an intent to deceive. The proposed complaint is devoid, for instance, of any allegations of fact to the effect that the Company or these defendants viewed the clinical hold as materially impeding

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[10] *Maldonado v. Dominguez*, 137 F.3d 1, 9 (1st Cir. 1998) ("allegations based on information and belief that [defendants] were aware of the risk of margin calls . . . [are] insufficient to meet 9(b)'s particularity requirement"); *Lirette*, 27 F. Supp. 2d at 282 (rejecting *scienter* allegations predicated merely on information and belief without supporting facts; the court would only consider "allegations supported by some document or statement on personal knowledge, rather than by information and belief"); *Colby v. Hologic, Inc.*, 817 F. Supp. 204, 212 (D. Mass. 1993) ("These allegations of *scienter* without specified sources or supporting facts are based implicitly upon information and belief alone, and so must be regarded as speculative and fatally defective").

the development of a trauma indication. While the Plaintiffs have (mistakenly) taken the view that, *ipso facto*, a clinical hold on a single proposed study must be material for any indication relating to that study, the view is inconsistent with FDA practice. As explained below, a clinical hold, even for "safety concerns," is little more than an initiation of a scientific dialogue with FDA which may result in an altered study design. It is not a *conclusion* about the safety of the product.

What is conspicuously absent from the proposed complaint is any reference to any internal memoranda, meeting minutes, discussions, deliberations or other evidence showing that Biopure, Moore or Richman viewed the clinical hold as remotely important. To the contrary, the complaint refers to statements by the Company which indicate (in text omitted from the complaint) that "the company did not publicly disclose its communications with the FDA about the proposed trauma protocol and investigational new drug application (IND) because it does not believe communications about proposed clinical trials are material prior to the initiation of a trial." *See* December 24, 2003 Press Release (cited in Prop. Compl. at ¶ 162) MTD App. Ex. 1.[11] The same press release indicated that a similar study as the one put on hold in the U.S. was conducted in South Africa. *Id.* At most, the proposed complaint alleges that these defendants made a judgment about whether the clinical hold was important or "bad news," but even a bad judgment does not amount to an intent to deceive. *See In re Miller Indus., Inc.*, 120 F. Supp. 2d 1371, 1382 (N.D. Ga. 2000) (mere judgment call about materiality does not establish *scienter*).

With respect to the FDA's July 30, 2003 letter concerning the BLA, it is difficult to see how these defendants can be deemed to have intentionally defrauded investors by failing to disclose that the letter was a "complete response letter" when the FDA itself did not identify the letter as such and the press release concerning the letter stated, as did FDA, that the FDA had "completed its review." *See* August 1, 2003 Press Release. MTD App. Ex. 22.

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[11] Documents previously submitted in Appendices in connection with the Defendants' Motion to Dismiss are cited to here as "MTD App. Ex. []".

III. NOTHING IN THE PROPOSED COMPLAINT CHANGES THE FACT THAT THERE WAS NO DUTY TO DISCLOSE THE TRAUMA CLINICAL HOLD

Even if, *arguendo*, the proposed complaint pled any basis for the information and belief allegations asserted, nothing in the complaint changes the fact that there was no duty to disclose the FDA's clinical hold on the single proposed study in trauma.

A. The FDA's Refusal To Lift the Clinical Hold Does Not Change The Fact That There Was No Duty To Disclose The Clinical Hold

In the proposed complaint, as in the pending complaint, the Plaintiffs have alleged that the Company's failure to disclose the clinical hold status of a single proposed protocol is actionable. The Plaintiffs erroneously equate the FDA's *concerns* regarding the use of Hemopure in a *particular study design* for a narrow group of individuals (trauma patients), with a *conclusion* that Hemopure could not be approved for any indication.[12] That fundamentally flawed assumption pervades the proposed complaint.

First, pursuant to 21 C.F.R. § 600.3(p), applicable to FDA biologics approval: "The word safety means the *relative* freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, *taking into consideration the character of the product in relation to the condition of the recipient at the time*." As Jane E. Henney, M.D, then Commissioner of Food and Drugs has explained: "Unlike in other areas of FDA's work, *there is no set formula or standard for a determination that a product is safe. Safety is a relative term. There is a continuum of uncertainty that is tolerated, depending on the seriousness of the illness.*"[13]

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[12] *See* Prop. Compl. ¶ 50("The FDA's safety concerns, as expressed on April 9, 2003, put Defendants on notice that FDA approval of the Hemopure BLA, a prerequisite to the first commercial distribution of Hemopure in the United States, was in jeopardy and serious doubt and that the FDA's decision would, unquestionably, be delayed beyond the time frames previously communicated by Defendants to the investing public.").

[13] 10th Annual PDA/FDA Joint Conference Keynote Address: "Strengthening The Science Base For Regulatory Decisions," Jane E. Henney, M.D, Commissioner of Food and Drugs, September 27, 1999, attached hereto as Ex. B.

Second, the clinical hold was issued with respect to the proposed clinical trial (study design) at issue, unless stated otherwise. *See* 21 C.F.R. § 312.40(a) ("The clinical hold order may apply to one or more of the investigations covered by an IND."). No fact is alleged indicating that the clinical hold here applied beyond this single, proposed study. When a clinical hold is imposed, the IND sponsor (here Biopure) and the FDA must resolve any outstanding concerns before the trial can proceed. *See* 21 CFR § 312.42(e). The ensuing scientific dialogue may result in modifications or redesign of the trial. *See id.; see also Guidance for Industry, Submitting and Reviewing Complete Responses to Clinical Holds*, FDA, CBER, CDER, Oct. 2000 (outlining process of scientific submission in response to clinical holds); *see Noble Asset Management* v. *Allos Therapeutics, Inc.*, CV No. 04-1030-RPM 2005 U.S. Dist. LEXIS 24452 at *7, 20-21 (D. Colo. Oct. 20, 2005) ("public documents provided by the FDA relating to its process [are] central to an evaluation of the claims" and accordingly, properly considered on motion to dismiss; FDA Guidance documents properly considered). In other words, a clinical hold and FDA's refusal to lift it represents a continuing scientific dialogue with the FDA concerning data, study design, dosage and other factors relevant to the safety of *the study*. When a biologic is deemed to present "safety concerns" in a particular clinical trial, it simply means that the FDA is evaluating the risks versus the benefits of the biologic within the particular study design. It is *not a conclusion* signaling non-approval of the *product*. The proposed complaint is devoid of allegations of fact to the contrary:

- There is not a single allegation of fact indicating that the clinical hold was issued with respect to the development or testing of Hemopure generally -- *i.e.* other than in the single proposed study at issue.

- There is not a single allegation of fact in the proposed complaint indicating that Hemopure has been deemed not approvable in any indication.

- There is not a single allegation of fact in the proposed complaint indicating that the FDA ever reached a *conclusion* that Hemopure was unsafe for *any* indication. (Again, safety concerns regarding a *study* is not a safety *conclusion* regarding the *product* or for an *indication*).

Defendants incorporate by reference their arguments in their previous motion to dismiss concerning the absence of a duty to disclose the scientific dialogue that is exchanged regularly between the FDA and drug sponsors. *See* Mem. in Support of Mtn. to Dismiss; Reply.[14] *See also Noble Asset Management.*, 2005 U.S. Dist. LEXIS 24452 at *21-22 ("The fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA.")

As the FDA's "safety concerns" were not conclusions, but rather, evinced a scientific dialogue, the Company was not required to, and in fact should not have, disclosed what it did not know about the FDA's state of mind in asking the questions.

B. There Was No Duty To Disclose The Clinical Hold Arising From The Company's Disclosed "Preparations" For A Trauma Indication

The Plaintiffs' theory appears to be an attempt to plead that the Defendants had a duty to disclose the clinical hold due to the fact that the Company disclosed that it was *preparing* to pursue a trauma indication, separate and apart from its BLA for orthopedic surgery. *See, e.g.*, Prop. Compl. ¶ 44. The Company's developmental steps in their preparations, such as submitting protocols or possible clinical trials, however, are not the stuff of required disclosure.

The First Circuit has recognized that, "[a] duty to disclose technical or *developmental problems* with a product may arise where a company makes *strongly optimistic or concrete statements* about that product that are in stark contrast to its internal reports." *Glassman v.*

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[14] *See* in particular, discussions of *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp 953, 966 (D. Md. 1995)(issuers "as a general proposition ha[ve] no duty to report [their] ongoing discussions with FDA . . . Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process. . . . Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process"); *In re Biogen Sec. Litig.*, 179 F.R.D. 37 (D. Mass. 1997) (defendants "had no duty to disclose [the FDA] reservations"); *Chu v. Sabratek Corp.*, 100 F. Supp. 2d 827, 834-35 (N.D. Ill. 2000) ("[s]imply receiving a number of letters from the FDA listing regulatory shortcomings does not portend ultimate FDA denial of the recipient's application").

Computervision Corp., 90 F.3d 617, 635 (1st Cir. 1996) (citations omitted) (emphasis added). But where the Company's "statements [do] not rise to the level of optimism or certainty that would make them materially misleading in the absence of disclosure of initial developmental problems the product was facing," such statements are not actionable as a matter of law. *Id.* That is particularly the case where the record demonstrates "*mild statements of hope, couched in strongly cautionary language*" -- such statements "cannot be said to have become materially misleading." *Id.*[15]

The principles underlying *Computervision* apply here. The Plaintiffs contend that the Company had a duty to disclose developmental problems it was experiencing with Hemopure in the trauma context, based on (in part) the Company's statements concerning the development of a trauma program. As in *Computervision*, the statements here were, at most, "mild statements of hope, couched in strongly cautionary language" that "cannot be said to have become materially misleading." *Id.*

1. The Company's Statements About A Trauma Indication Were Neither "Strongly Optimistic" Nor "Concrete"

The Company's statements about a trauma indication were neither "strongly optimistic" nor "concrete." To the contrary, the Company, at most, disclosed its *intentions* to develop Hemopure for a *potential* use in trauma.

In its January 29, 2003 Form 10-K, the Company indicated generally:

> Biopure is also developing Hemopure for ***potential use*** in trauma and other medical applications. In September 2002, the U.S. Department of the Army awarded Biopure a

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15 In *Computervision*, the company stated that it "expected" its development-stage product CADDS 5 "to broaden the number of customers in existing accounts as well as attract new customers," and that it "believe[d] that CADDS 4X and CADDS 5 are likely to be used in tandem by major accounts in the foreseeable future." *Id.* The court deemed that these statements, whether read in isolation or in the context of Computervision's warnings that the product may not be accepted by the market and may need further enhancements, suggested "at most, the hope that CADDS 5 will eventually gain acceptance in the market. Such hope is not unusual for a company releasing a new product." *Id.* "[I]n this case, the statements about CADDS 5 in the Prospectus were not so optimistic as to be materially misleading about the existence of developmental or commercial difficulties with CADDS 5. To the contrary, the Prospectus frequently alludes to the uncertainties associated with the release of a new product." *Id.*

> $908,900 grant for a standard therapy controlled, Phase II clinical trial evaluating the safety and tolerability of the product in trauma patients. The Company has identified trauma as its next ***clinical development*** priority and is working with a committee of independent civilian and military trauma experts to broaden its trauma program.

January 29, 2003 Form 10-K at 1 (emphasis added) MTD App. Ex. 3. There is nothing strongly optimistic about the "identification" of a "potential use in trauma" as a "clinical development priority," let alone concrete.

The Company also made the following statement:

> The Company ***expects to initiate additional pre-clinical and clinical trials*** this year to expand the indications for Hemopure beyond surgery.
>
> We are also developing Hemopure for ***potential use in trauma*** and other medical applications.

Forms S-3 dated April 11, 2003, April 16, 2003, June 19, 2003, July 2, 2003 and August 22, 2003, MTD App. Exs. 8, 15-18. An "expectation" to initiate clinical trials in connection with "develop[ing]" a "potential use" in trauma is neither strongly optimistic nor concrete.

Furthermore, the general statements about potential *future* development were *not* about the in-hospital indication or the in-hospital trial that was on hold. On their face, those general disclosures concerned an out-of-hospital indication.

The Plaintiffs also criticize a selective excerpt of a dialogue between an investor and Defendant Moore during a May 2003 investor conference call. In particular, the Plaintiffs purport to quote Defendant Moore as saying that "Parkman Hospital is going to be our initial clinical center to conduct the already announced in-hospital trauma trials that will set us up for subsequent pre-hospital trials to establish an additional trauma indication for Hemopure," claiming that the forward looking statement is misleading for failure to disclose the clinical hold. Compl. ¶¶ 73, 74. The *full* discussion, however, reveals that Defendant Moore's statement was actually in response to a question mistakenly asserting that clinical trials had already begun in

trauma at Parkman.[16] *See* CCBN Street Events, BPUR Q-2 Earnings Call Tr. May 22, 2003, MTD App. Ex. 27. Accordingly, in context, Defendant Moore's response was one to correct the caller's erroneous statement.[17]

In any event, there is nothing "strongly optimistic" or "concrete" about the development of a trauma indication in Defendant Moore's statements. Indeed, the statement indicates that in-hospital clinical trials were merely a preliminary step ("this will set us up") for "subsequent pre-Hospital trials to establish an additional trauma indication." Moore's statement -- concerning a preliminary step, that would be followed by another preliminary step, that could lead to a new indication -- is hardly a "strongly optimistic" or "concrete" statement about a future trauma indication requiring disclosure of developmental difficulties.[18]

2. At Most, The Company's "Mild Statements Of Hope" Were "Couched In Strongly Cautionary Language"

As shown above, the Company's statements regarding a "potential use in trauma" as its "clinical development priority" conveyed nothing more than a hope to develop a trauma indication for Hemopure. At the same time that the Company was expressing its hopes for a

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16 *In Re ATI Technologies, Inc.*, 216 F. Supp. 2d 418, 431 (E.D. Pa 2002) (noting the importance of looking to the entirety of conference call transcript, and noting that "a plaintiff may not excise a statement from a transcript and then protest when a defendant mobilizes the entire transcript. . . .")

17 *Miller v. Champion Enterprises*, 346 F.3d 660 (6th. Cir. 2003) (holding no additional disclosure required based on questions raised during call: the "topics discussed during the conference call were not things that defendants chose to discuss. They were asked questions by investors about repurchase obligations and bankruptcies, which it appears they endeavored to answer truthfully as to the current state of affairs. Furthermore, they studiously avoided speaking about future events.")

18 Nor did the comment about Parkman require disclosure of the hold because the trial referred to was on hold. Apart from the limited disclosure obligations arising as a matter of law from responses to investor questions during an investor call, *see* n. 17 above, as noted, the hold did not mean that the trial could

potential indication, throughout 2003, the Company was careful to warn investors that any potential new indication would require new clinical trials to be approved by the FDA, with no guarantees of FDA approval:

> ***We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication***
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. ***To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully. We cannot guarantee that the FDA will approve Hemopure for any indication.*** We can only promote Hemopure in the United States for indications that have been approved by the FDA. The FDA may require a label cautioning against Hemopure's use for indications for which it has not been approved.

See January 31, 2003 Form 10-Q (emphasis added) MTD App. Ex. 2.

The Company also specifically warned investors about possible "uncertainties" and "delays" related to clinical trials:

> [E]xcept for strictly historical information contained herein, matters discussed in this report constitute forward-looking statements. ***There can be no assurance*** that Biopure will be able to commercially develop Hemopure, ***that necessary regulatory approvals will be obtained, that anticipated milestones will be met in the expected timetable, that any clinical regulatory approvals will be obtained, that any clinical trials will be successful,*** or that any approved product will attain market acceptance and be manufactured and sold in the quantities anticipated. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the Company's operations and business environment. ***These risks include,*** without limitation, the availability of sufficient financing to support operations, the Company's stage of product development, history of operating losses, accumulating deficits, and ***uncertainties and possible delays related to clinical trials and regulatory approvals,*** possible healthcare reform, manufacturing capability, market acceptance and competition.

See January 31, 2003 Form 10-Q; April 30, 2003 Form 10-Q MTD App. Exs. 2, 19 .

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never proceed. Indeed, at the time of the call, the Company was in negotiations with FDA to get the hold lifted. Prop. Compl. ¶67.

These express statements, warning that FDA approval of clinical trials is required, that the trials may not be successful, that there are potential uncertainties and delays inherent in the process and that FDA approval may never be achieved, were made alongside the Company's expressed hopes to expand Hemopure's indications. As in *Computervision*, the Company's statements are not actionable. To the contrary, these statements concerned "soft" information -- expectations and intentions for future plans -- and bespoke caution. *See also Noble Asset Management*, 2005 U.S. Dist. LEXIS 24452 at *26-27 (statements that allegedly "fostered the impression that FDA approval would be forthcoming" in the face of FDA's negative communications held not actionable because the company's "cautionary statements [that] addressed the possibilities that test data could be subject to varying interpretations, that the Company might not be able to demonstrate efficacy, that a second Phase 3 trial might be necessary, and that FDA approval might be delayed or not obtained at all," were protected under PSLRA safe harbor).

IV. THERE WAS NO DUTY TO DISCLOSE THAT THE FDA'S JULY 30 LETTER WAS ALLEGEDLY A "COMPLETE RESPONSE LETTER"

The Plaintiffs' copying of the SEC complaint has resulted in a new theory of liability being injected here -- allegations of fraud because the Defendants did not state that the FDA's July 30, 2003 BLA Letter was a Complete Response Letter ("CRL"). The most glaring deficiency laden in the Plaintiffs' contention is the indisputable fact that *the BLA Letter did not identify itself as a CRL*. *See* Prop. Compl. Ex. B (the words "complete response letter" appear nowhere). The Plaintiffs seek to predicate a fraud claim on a failure to disclose not that which was communicated by the FDA in its BLA Letter, but rather, that which was *not communicated.* The theory is entirely antithetical to fundamental principles of disclosure requirements.

Even if the FDA did intend the July 30, 2003 BLA Letter to be a "complete response letter," the label in and of itself is insignificant. A CRL label in and of itself is patently immaterial to ultimate FDA approval, in the words of the FDA: "*[i]ssuance of complete response letters . . . [carry] no implication as to the ultimate approvability of the application*."

See Proposed Rules Department Of Health And Human Services: FDA 21 CFR Parts 312, 314, 600, and 601 Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications Tuesday, July 20, 2004 69 FR 43351-01, 2004 WL 1599720 *43352 (page 5 of 40 in attachment), ("Proposed Rules") (comments on proposed regulation defining complete response letters) attached hereto as Ex. C (emphasis added).

Label aside, the Company's August 1 Press Release quoted or accurately summarized the BLA Letter:

The July 30 BLA Letter	**The August 1 Press Release**
• "(CBER) has *completed the review* of all submissions made relating to your Biologics License Application."	• "(FDA) has *completed its review* of the company's biologics license application . . ."
• The letter asks for information about clinical and preclinical data and has some comments on labeling.	• "The FDA has issued a letter requesting additional information."… "The letter focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling."
• "Please note our review clock has been suspended with the issuance of this letter." The letter was sent on July 30, 2003 but the deadline was August 29, 2003, thirty days later. The letter stated the review clock "will [not] be reactivated until all deficiencies have been addressed."	• "With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock until Biopure submits a complete response."
• The letter does not request additional clinical trials.	• "It does not request additional clinical trials."

Other than the accurate phrases and descriptions lifted from the July 30 BLA Letter, the August 1 press release contains a quote from Mr. Moore.

The quote reads as follows:

> We're encouraged that the FDA has finished its review and provided comprehensive feedback in advance of the formal action due date. By maintaining 30 days on the review clock, the FDA is encouraging us to work with them to complete the approval process as quickly as possible," said Biopure

> president and CEO Thomas A. Moore. "We'll work with the Agency to address the remaining questions and will provide our answers as expeditiously as possible."

MTD App. Ex. 22. This is a soft statement of corporate optimism (*i.e.*, "we're encouraged") and future intent. As courts have aptly recognized, "[p]eople in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129-30 (2d Cir. 1994) *superceded by statute on other grounds as recognized in In re Paracelsus*, 61 F. Supp. 2d 591 (S.D. Tex. 1998). Furthermore, Plaintiffs have not alleged any fact to show that Mr. Moore did not believe what he said -- there are no allegations of *scienter*. Accordingly, such statements are not actionable as a matter of law.[19]

Apart from quibbles about corporate optimism, the Plaintiffs take issue with what they believe the Press Release *should have disclosed* concerning speculative projections for what the letter meant for Biopure, apparently based upon what the FDA *meant to say* in its letter. The Plaintiffs complain that the Company should have disclosed that the issuance of the letter implicated a 6 month future FDA review cycle, and that the Company's reference to "thirty days remaining" in the review cycle was therefore misleading. Prop. Compl. ¶ 110.

Indisputably, the letter itself says nothing of future FDA review timetables, and indisputably, the letter was received 30 days prior to the end of the review cycle. Accordingly,

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[19] *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1217 (1st Cir. 1996) *superceded by statute on other grounds as recognized in Greebel v. FTP Software, Inc.*, 194 F.3d 185 (1st Cir. 1999) ("Courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace--loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available"); *Gross v. Summa Four, Inc.*, No. Civ. C-94-364-B 1995 WL 806823, *11 (D.N.H. Nov. 8, 1995) ("Statements, however, that are general, vague, or lack specificity, or are not guarantees, even if made without a reasonable basis, are not actionable because a reasonable investor would not rely on them."); *Rand v. Cullinet Software, Inc.*, 847 F. Supp. 200, 209 (D. Mass. 1994) (statements such as "we are optimistic about the future" are "too general for a reasonable investor to have considered them to be important "); *Noble Asset Management.*, 2005 U.S. Dist. LEXIS 24452 at *23 (optimistic statements concerning FDA approval not actionable; there was no statement guaranteeing approval).

the Plaintiffs' theory would impose a disclosure obligation to speculate that the FDA meant to convey information about future review periods. Apart from the absence of any legal principle requiring an issuer to speculate about the meaning of FDA communications, "[t]he federal securities laws impose no obligation upon an issuer to disclose forward-looking information such as internal projections, estimates of future performance, forecasts, budgets, and similar data." *Glassman*, 90 F.3d at 631; *see In re Convergent Technologies Sec. Litig.*, 948 F.2d 507, 516 (9th Cir. 1991) (no duty to disclose uncertain projections); *Walker v. Action Indust., Inc.*, 802 F.2d 703, 709-10 (4th Cir. 1986) (no duty to disclose financial projections that were uncertain and misleading in nature); *Karacand v. Edwards*, 53 F. Supp. 2d 1236, 1243-44 (D. Utah 1999) ("when defendants voluntarily disclose information, they have a duty only to make the disclosure at the time 'complete and accurate'" but "[t]his obligation, however, carries with it no duty to make projections about the future."). The Company here chose not to speculate about what FDA might have intended to say, nor disclose future projections for FDA actions based on such speculation.

Moreover, for the same reasons that the Company's statements about a potential trauma indication were not actionable under the PSLRA's safe harbor, so too were the forward looking aspects of the Company's statements concerning any implications of the July 30, 2003 letter not actionable.

V. THE PROPOSED COMPLAINT'S CONTROL PERSON AND INSIDER TRADING CLAIMS FAIL

As the proposed complaint fails to state a predicate Section 10b claim, so too does the claims for control person liability (Count II) and insider trading (Count III). *Guerra v. Teradyne Inc.*, No. Civ. A. 01-11789-NG 2004 WL 1467065 *28 (D. Mass. Jan. 16, 2004) ("Where, as here, the complaint fails to allege an underlying violation of the securities laws, the Section 20(a) claims should be dismissed."); *Jackson Nat. Life Ins. Co. v. Merrill Lynch & Co., Inc.*, 32 F.3d 697 (2d Cir. 1994) (insider trading claim fails must be predicated on 10b claim).

CONCLUSION

For the forgoing reasons, the Defendants respectfully request that Plaintiffs' motion for leave to amend the complaint be denied, and the pending complaint be dismissed with prejudice.

January 23, 2006

Respectfully submitted,

BIOPURE CORPORATION, THOMAS A. MOORE, HOWARD P. RICHMAN, RONALD RICHARDS, CARL W. RAUSCH, CHARLES A. SANDERS AND J. RICHARD CROUT

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RULE 7.1(a)(2) CERTIFICATION

I hereby certify that counsel for Defendants conferred with counsel for Plaintiffs in good faith to resolve or narrow the issues presented in this motion, and the Plaintiffs do not consent to the relief sought herein.

/s/ Michael D. Blanchard
Michael D. Blanchard

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above pleading was electronically served upon the attorneys of record for all parties on January 23, 2006.

/s/ Michael D. Blanchard
Michael D. Blanchard